

REMARKS

This Request for Continued Examination Re-opening Prosecution and Response to New Rejection Under 37 C.F.R. §41.50(b) is respectfully submitted in response to the Decision on Appeal rendered May 4, 2010, in which a period for response of two (2) months was set. It is timely in view of the fact that July 4, 2010 falls on a Sunday and July 5, 2010 is a Federal holiday. Applicants request reconsideration in light of the following remarks, the Request for Continued Examination and Declaration of Yaping Hu respectfully submitted herewith.

Claim 75 has been amended to include reference to the trypsin inhibitory activity level of the compositions useful in the methods of applicants' invention. Basis for this amendment may be found in the Specification at p. 31, l. 25 to p. 32, l. 21 in Table 2. The percent of trypsin inhibition may be calculated from the "% Ingestion" column by subtracting the % Ingestion from 100%.

The Decision on Appeal of May 4, 2010 rejected claims 75-84 under 35 U.S.C. 102(b) as being anticipated by JP Patent Application No. Hei-8-143442 to Matsuura et al (JP '442). Applicants respectfully request reconsideration of this rejection in view of the foregoing amendments to the claims and the ensuing discussion.

The Decision on Appeal bases the foregoing rejection on a review of Matsuura Example 1 in which a soymilk preparation was made and applied to subjects having skin conditions. [Decision on Appeal, pp. 4-5]. The Decision on Appeal further cited Van der Ven and Kwok to show the time and temperature requirements for destroying trypsin inhibitors in soy preparations [Decision on Appeal, pp. 6-7]. The Decision on Appeal concluded that, without additional testing, the soybean extract prepared in accordance with Matsuura would have inherently contained trypsin inhibitory activity. [Decision on Appeal, p. 11]

Applicants respectfully request reconsideration of the foregoing rejection in view of the amendments to the claims, the attached Declaration of Yaping Hu and the ensuing discussion. As recited in the Decision on Appeal, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Vendegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). However, applicants respectfully contend that demonstrating inherency "requires that the missing descriptive material is '*necessarily present*,' not merely probably or possibly present, in the prior art." *Trintec Industries, Inc. v. Tap-U.S.A. Corporation*, 295 F.3d 1292, 1295 (Fed. Cir. 2002). (emphasis added)

As will be seen in the ensuing discussion and in the accompanying Declaration of Yaping Hu (hereinafter, "Hu Declaration"), respectfully submitted concurrently herewith, the limitations

of the claims as amended are *not* necessarily present in the Matsuura publication. Applicants therefore respectfully request reconsideration of the new grounds of rejection set forth in the Decision on Appeal.

Applicants also note that both the Kwok and Van der Ven references cited in the Decision on Appeal were published *after* (2002 and 2005 respectively) the filing date of the above-captioned patent application.

As described in the Hu Declaration, soy preparations were made following the Matsuura publication as closely as possible. In Examples A and B, whole soy beans were dry-heated at 75°C for two hours, then pressed and dehulled. 20 g of dehulled beans were ground in a blender for four minutes with 200 ml of water at 5°C and the slurry heated to 100°C for 30 seconds. [Hu Declaration, ¶3] This process was performed in accordance with the Matsuura Example 1. [Matsuura Translation, ¶0012, p. 9]

Additional examples B-K were also prepared as set forth in the Hu Declaration, following a range of various conditions described in the Matsuura publication, including soaking whole soybeans in 200 ml water for five minutes at 100°C [Example G, Hu Declaration, ¶3], soaking whole soybeans in 200 ml water for 20 hours at 5°C [Example H, Hu Declaration, ¶3], soaking whole soybeans in 200 ml water for 20 hours at 20°C [Example J, Hu Declaration, ¶3] and soaking whole soybeans in 200 ml water at 5°C overnight, grinding in a blender at 20°C, heating the slurry for five minutes at 75°C and reheating the slurry to 100°C for five minutes [Example K, Hu Declaration, ¶3]. Applicants respectfully submit that the examples were attempted in order to view the result of a range of soaking temperatures and times. Thus, Examples C-K were performed with these ranges in mind, but were not specifically intended to replicate specific examples set forth in Matsuura.

Applicants also respectfully note that the test of trypsin inhibition as described in the Specification as filed at p. 31, l. 25 through p. 32, l. 20 has a fairly large range of standard deviation, or margin of error. For example, in Table 2 of the Specification at p. 32, l. 15, the margin of error ranges from 11 to 15%. In fact, as set forth in the Hu Declaration, “Because of [the] assay variability, results of this assay that are at or below 18-20% are considered as below the margins of detection of the reliable threshold to describe real biological activity.” [Hu Declaration, ¶4]

Trypsin inhibition activity was tested for Examples A-K set forth in the Hu Declaration in comparison with soy trypsin inhibitor (“STI”) samples and a soy preparation prepared in accordance with the above-captioned patent application [Hu Declaration, ¶4]. It was determined that while the 0.05% STI sample and the soy sample prepared in accordance with the above-captioned patent application had fairly significant % inhibition rates (respectively, 84% and 57.9%), Examples A-J performed in accordance with the teachings of the Matsuura publication had negligible inhibition rates. In addition, the 0.005% STI sample and Example K demonstrated trypsin inhibition rates at 15.6% and 15.2% respectively, which are within the margin of error and might represent little or no trypsin inhibitory activity. [Hu Declaration, ¶5]. Thus, it is unclear whether any of the preparations of Matsuura have *any* trypsin inhibitory activity.

Based upon the data set forth in the Hu Declaration, applicants respectfully submit that following the teachings of Matsuura would not *necessarily* produce soy preparations containing soy trypsin activity. Certainly, the preparations of Examples A and B, which were most duplicative of the process described in Example 1 of Matsuura, had *no* trypsin inhibitory activity or an extremely tiny measurement of such activity (1.3%, which is well under the margin of error). Therefore, one of ordinary skill in the art, following Matsuura, would not *necessarily* make a preparation containing trypsin inhibitory activity sufficient to be effective in decreasing phagocytosis or ICAM-1 expression and result in the therapeutic outcomes of the claimed method of use. Thus, applicants respectfully submit that the Matsuura publication would not inherently anticipate the compositions and methods of applicants’ invention.

Applicants therefore respectfully submit that Matsuura does not anticipate the limitations of the claims of the above-captioned application in accordance with 35 U.S.C. §102 and respectfully request reconsideration of the foregoing rejection in view of the foregoing discussion, amendments to the claims and attached Declaration of Yaping Hu submitted concurrently herewith.

For the foregoing reasons, applicants respectfully submit that the above-captioned application is now in condition for allowance. Accordingly, favorable reconsideration of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750.

Respectfully submitted,

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